REMARKS

I. Petition for Extension of Time

Applicants herewith petition the Commissioner for Patents to extend the time for response to the Office Action mailed 27 February 2007 for three (3) months from 27 May 2007 to 27 August 2007. Authorization is given to charge the extension of time fee of $1020.00 (37 C.F.R. §1.136 and §1.17) to Deposit Account No. 23-1703. Any deficiency or overpayment should be charged or credited to the above numbered deposit account.

II. Claim Amendments

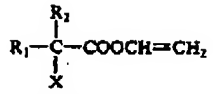
Claims 3-6 have been amended to recite that the claimed aqueous polymer dispersion, which is prepared by polymerizing a mixture of the recited monomers in water and in the presence of an emulsifying agent, is substantially free of residual emulsifying agent which is removed after the polymerization reaction. Support for the amendment is found in the specification at: [0050], [0060] and [0061] of the published patent application US 2005/0256255, and Examples 1, 2 and 8.

No new matter has been introduced by any of the claim amendments.

III. Claim Rejections – 35 U.S.C. §102

Claims 3, 4 and 31 are rejected under 35 U.S.C. §102(b) as being anticipated by US 4,056,497 to Reinecke et al. ("Reinecke"). Reinecke discloses crosslinkable and crosslinked acrylic ester copolymers prepared from the following mixture of monomers:

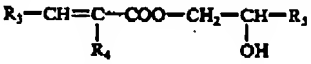
> a. 60 to 95% by weight, calculated on the monomer mixture, of at least one acrylic acid ester and/or methacrylic acid ester of a saturated aliphatic alcohol having from 1 to 20 carbon atoms,
>
> b. 0 to 40% by weight, calculated on the monomer mixture, of monomers the homopolymers of which have second order transition temperature of from -40°C to +150°C,
>
> c. 0.1 to 10% by weight, calculated on the monomer mixture, of an α-haloalkane carboxylic acid vinyl ester of the formula (I)



wherein R_1 and R_2 each represents hydrogen or an alkyl radical having from 1 to 5 carbon atoms and X is fluorine, chlorine, bromine or iodine,

d. 0.1 to 10% by weight, calculated on the monomer mixture of, α,β-ethylenically unsaturated carboxylic acids having from 3 to 8 carbon atoms or their partial ester with saturated aliphatic alcohols having from 1 to 20 carbon atoms and

e. 0 to 10% by weight, calculated on the monomer mixture, of monomers containing hydroxyl groups and having the formula (II)



wherein R_3 is hydrogen, a methyl group or the group $-COOR_6$, R_4 and R_5 each is hydrogen or a methyl group and R_6 is hydrogen or an alkyl group having from 1 to 12 carbon atoms.

(col. 1, line 57, to col. 2, line 32)

As acknowledged by the Examiner on page 3 of the Office Action, Reinecke's dispersions are prepared by free radical polymerization ***using emulsifiers***, protective colloids and, optionally, regulators (col. 3, lines 12-17).

Anticipation requires that each and every feature of the claimed invention be found in a single reference. For the following reasons, Reinecke fails as an anticipatory reference.

Each of claims 3, 4 and 31 expressly recites that the claimed aqueous polymer dispersion is substantially free of residual emulsifying agent. Applicants submit that this limitation is not a product-by-process limitation but is a characterizing property of the claimed dispersion. Specifically, after the polymerization reaction is complete, the emulsifying agent is removed, e.g., by dialysis, microfiltration, serum exchange, etc., to provide the claimed aqueous polymer dispersion that is substantially free of residual amounts of the emulsifying agent.

Reinecke discloses that the prior art aqueous dispersion is prepared by free radical polymerization using emulsifiers, protective colloids and, optionally, regulators. However, Reinecke does not disclose, either expressly or inherently, that the emulsifying agent is partially

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or fully removed after polymerization. Accordingly, there is no disclosure by Reinecke of an aqueous polymer dispersion that is substantially free of residual emulsifying agent.

As noted in [0050] of the published patent application US 2005/0256255, the presence of residual emulsifier causes instability of the film coat prepared from the dispersion which leads to deterioration of the release properties of the coated drug on storage. Claims 3, 4 and 31 expressly recite as a feature that the claimed aqueous polymer dispersion is substantially free of residual emulsifying agent which is not disclosed by Reinecke. Therefore, Reinecke fails as an anticipatory reference.

Withdrawal of the §102 as to claims 3, 4 and 31 is requested.

IV. Claim Rejections – 35 U.S.C. §§102/103

Claims 5 and 6 are rejected under 35 U.S.C. §102(b) as being anticipated by or, in the alternative, under 35 U.S.C. §103(a) as being obvious over Reinecke.

Claims 5 and 6 have also been amended to expressly recite that the claimed aqueous polymer dispersion is substantially free of residual emulsifying agent. As discussed in Section III, above, the claim limitation "substantially free of residual emulsifying agent" is not disclosed by Reinecke. Therefore, Reinecke fails to anticipate since the reference does not disclose each and every feature of the claimed invention.

Nor is there any appreciation by Reinecke to prepare an aqueous polymer dispersion that is substantially free of residual emulsifying agent to obtain an improved film coating material that is stable with respect to agglomeration and provides good delayed release properties that are not affected by storage. As such a *prima facie* case of obviousness has not been established.

Advantageously, as disclosed at [0050] of the published patent application US 2005/0256255, the claimed aqueous polymer dispersion, which is substantially free of residual emulsifying agent, provides improved film coating properties, e.g., stability, good delayed release properties that are not affected by storage, etc. In contrast, it is reasonable to expect that the presence of the residual emulsifier found present in the aqueous polymer dispersion disclosed by Reinecke, when used as a film coating material, will cause instability of the film coat and a deterioration of the release properties of the coated drug on storage.

For all of the foregoing reasons, Applicants respectfully submit that the claimed invention is novel and nonobvious in view of Reinecke. Withdrawal of the claims rejections under 35 U.S.C. §§ 102/103 is requested.

V. Claim Rejections – 35 U.S.C. §103

a. claims 7-8

Claims 7 and 8 are rejected under 35 U.S.C. §103(a) as being unpatentable over US 3,234,039 to Lalk et al. ("Lalk") in view US 3,086,956 to Armen et al. ("Armen") as evidenced by US 3,717,689 to Tanaka et al. ("Tanaka").

The transition phrase "consisting of" is used to define the aqueous polymer dispersion of claims 7 and 8. Specifically, according to these claims, the claimed aqueous polymer dispersion consists of the polymerized mixture of the expressly recited monomers: (1) an acrylic acid or an ester thereof; (b) a methacrylic acid or an ester thereof ; and (c) a polymerizable surfactant. Except for impurities ordinarily associated with this polymerized mixture, all other ingredients are excluded. In this regard, the Examiner's attention is directed to M.P.E.P. §2111.03, "Transitional Phrases [R-3] - 2100 Patentability".

Therefore, by definition, the ingredients of the claimed aqueous polymer dispersion do not include a residual emulsifier. This construction is consistent with the disclosure at [0050] of the published patent application US 2005/0256255 where it is provided that the inventors surprisingly found that the reduction or elimination of any residual emulsifier in the dispersion results in a film coating dispersion/composition that advantageously improves the physical properties of the final film coating, e.g., stability, release properties, etc.

In contrast to the aqueous polymer dispersion defined by claims 7 and 8, the aqueous dispersion disclosed by Lalk requires a water-soluble emulsifying agent (col. 3, line 17). Generally, the amount of the emulsifying agent is between 2.0 percent and about 12 percent of the weight of the mixture of monomers (col. 4, lines 15-17). Lalk discloses typical emulsifying agents at column 4, lines 17-28. A specifically disclosed emulsifier is Triton-200 at column 4, line 65.

Although Lalk discloses at column 4, lines 44-47, that "[v]olatile residual monomers can be reduced or removed...if so desired", there is no teaching by Lalk that the emulsifier should be

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reduced or eliminated after polymerization. In fact, Lalk teaches that the aqueous polymer dispersion to be applied as an exterior wood primer contains an emulsifying agent (col. 4, lines 56-66). In any event, it would appear that the emulsifiers disclosed by Lalk as typical emulsifying agents are not volatile. At least the product information provided by Dow does not suggest that Triton-200 is not and would not be a so-called volatile residual monomer. Accordingly, in the absence of impermissible hindsight, Lalk fails to provide any motivation or suggestion to prepare the aqueous polymer dispersion of claims 7 and 8 which do not include an emulsifier as an expressly recited ingredient.

The Examiner cites Armen and Tanaka for the alleged disclosure of the monomer of the formula (I) as recited in claim 8. This alleged disclosure does not overcome the deficiencies of the primary reference to Lalk to suggest the claimed invention.

For all of the foregoing reasons, a *prima facie* case of obviousness has not been established. Withdrawal of §103 rejection of claims 7 and 8 is requested.

b. claims 9-14

Claims 9-14 are rejected under 35 U.S.C. §103(a) as being unpatentable over Reinecke in view of US 5,055,306 to Barry et al. ("Barry").

Barry is directed to a sustained-release formulation in the form of effervescent or water-dispersible tablets (col. 1, lines 5-7). In the paragraph bridging columns 4 and 5, it is stated that "sustained-release formulations of pharmacologically active substances have not previously been presented, or at least successfully presented, in the form or effervescent or water-dispersible tablets". To solve this problem, Barry discloses a specific coating covering substantially the whole surface of a core containing granules of a pharmaceutically active and effervescent or water-dispersible ingredients. As disclosed at column 3, lines 48-53, the coating comprises the following: 100 parts of a water insoluble but water swellable acrylic polymer, and from 20 to 70 parts of a water soluble hydroxylated cellulose derivative.

The Examiner alleges that it would have been obvious at the time the claimed invention was made to replace the coating disclosed by Barry with one comprised of the acrylic ester copolymer disclosed by Reinecke to arrive at the claimed invention.

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Each of the rejected claims 9-14 is dependent, either directly or indirectly, any one of claims 3-8 which are directed to an aqueous polymer dispersion.

When claims 9-14 are dependent on any one of claims 3-6, Applicants submit that the claimed pharmaceutical formulation is patentable over the combination of Reinecke and Barry. It has been established in the preceding Sections III and IV, above, that Reinecke does not anticipate or suggest the claimed aqueous polymer dispersion of claims 3-6 according to which the claimed aqueous polymer dispersion is substantially free of residual emulsifying agent. As a result, the claimed aqueous polymer dispersion surprisingly and advantageously provides improved film coating properties, e.g., stability, good delayed release properties that are not affected by storage, etc. It is submitted, therefore, that claims 9-14 when dependent on any one of claims 3-6 represent a patentable improvement over the prior art dispersions, such as disclosed by Reinecke, containing residual emulsifying agent. Barry does not overcome the deficiencies of Reinecke to suggest the claimed pharmaceutical coating film and formulation of claims 9-14 when these claims are dependent on claims 3-6.

Similarly, when claims 9-14 are dependent on claim 7 or 8, Applicants submit that the claimed pharmaceutical formulation is patentable over the combination of Lalk and Armen as evidenced by Tanaka. It has been established in the preceding Sections V(a), above, that Lalk does not disclose or suggest the aqueous polymer dispersion of claims 7 and 8 which do not include an emulsifier as an expressly recited ingredient. Instead, Lalk discloses a dispersion containing an emulsifier in an amount between 2.0 percent to about 12 percent by weight of the mixture of monomers. And there is no motivation or suggestion by Lalk to reduce or remove any residual emulsifier since none of the emulsifying agents disclosed by Lalk as typical emulsifiers appears to be volatile. Finally, Lalk does not provide a scintilla of any suggestion of using the prior art dispersion as a ***pharmaceutical film coating*** for use with a ***pharmaceutical dosage form***. Rather, Lalk is directed to latex finishing systems for exterior wood surfaces. Each of Armen and Tanaka are generally directed to polymer compositions for forming fibers. As such, neither Armen nor Tanaka overcome the deficiencies of Lalk to suggest the claimed pharmaceutical coating film and pharmaceutical formulation of claims 9-14 when these claims are dependent on claim 7 or 8.

For all of the foregoing reasons, a *prima facie* case of obviousness has not been established. Withdrawal of §103 rejection of claims 9-14 is requested.

c. claims 15 and 16

Claims 15 and 16 are rejected under 35 U.S.C. §103(a) as being unpatentable over Reinecke in combination with Barry, US 5,939,578 to Chen ("Chen") and US 4,957,745 to Jonsson et al. ("Jonsson").

Claims 15 and 16 are directed to the active ingredients of the claimed pharmaceutical formulation. The Examiner notes that Barry does not teach the beta-blocking adrenergic agent to be metoprolol salts such as tartrate, succinate, fumarate or benzoate salt. For this purpose, the Examiner relies on Chen and Jonsson.

Claims 15 and 16 are dependent on claim 14 which is itself indirectly dependent on any one of claims 3-8. The patentability of claim 14 is discussed in the preceding Section V(b), above.

When claim 14 is dependent on any one of claims 3-6, Applicants submit that neither Chen nor Jonsson overcomes the failure of the combination of Reinecke and Barry to render the pharmaceutical formulation of claims 15-16 obvious for the reasons given in the preceding Section V(b), above. Similarly, when claim 14 is dependent on claim 7 or 8, Applicants submit that neither Armen nor Tanaka overcome the deficiencies of Lalk to suggest the pharmaceutical formulation of claims 15-16 for the reasons given in the preceding Section V(b), above.

Withdrawal of the §103 rejection of claims 15 and 16 is requested.

d. claims 27-30 and 32

Claims 27-30 and 32 are rejected under 35 U.S.C. §103(a) as being unpatentable over Reinecke in combination with US 6,646,046 to Contrada et al. ("Contrada") as further evidenced by GB 1 141 165 ("Zellstoffwerke").

With respect to the limitations of dependent claims 27-30 and 32, the Examiner acknowledges that Reinecke does not teach the repeating units in component (e), i.e., Formula II, and an alkoxy group with C1-20 for the terminal group. For this purpose, the Examiner relies on Contrada and Zellstoffwerke.

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Contrada is directed to an aqueous pressure-sensitive adhesive composition. The Examiner relies specifically on the disclosure of the monomer M_1 disclosed at column 3, lines 38-54. Zellstoffwerke is directed to the manufacture of acrylic films. The Examiner relies on the disclosure by Zellstoffwerke of an ester of a polyethoxylated product containing at least one acrylic or methacrylic ester group. The Examiner alleges that the cited compounds of Contrada and Zellstoffwerke, respectively, encompass component (e) of Reinecke.

Each of claims 27-30 and 32 is directly dependent on claim 4, 6 or 8 directed to an aqueous polymer dispersion.

It has been established in the preceding Sections III and IV, above, that Reinecke does not anticipate or render obvious the claimed aqueous polymer dispersion of claims 4 and 6. With regard to the claim 27-30 and 32 when they are dependent on claim 4 or 6, the Examiner's reliance on Contrada and Zellstoffwerke fails to overcome the deficiencies of Reinecke. Therefore, it is submitted that the combination of Reinecke, Contrada and Zellstoffwerke does not suggest the aqueous polymer dispersion of claims 27-30 and 32 which include the limitations of claim 4 or 6 from which they depend.

And it has been established in Section V(a), above, that the cited combination of Lalk, Armen and Tanaka, whether taken alone or in combination, does not suggest the claimed aqueous polymer dispersion of claim 8. Therefore, it is submitted that the combination of Lalk and Armen as evidenced by Tanaka does not suggest the aqueous polymer dispersion of claims 27-30 and 32 which include the limitations of claim 8 from which they depend.

Withdrawal of the §103 rejection of claims 27-30 and 32 is requested.

Conclusion

In view of the claim amendments and remarks herein, the application is in condition for allowance.

Authorization is hereby given to charge any fee due in connection with this communication to Deposit Account No. 23-1703.

Dated: 27 August 2007

Respectfully submitted,

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